

IN THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

Claim 1 (currently amended): A pharmaceutical aerosol formulation to be administered by a pressurized metered dose inhaler, which consists of:

salmeterol, a stereoisomer thereof, or a physiologically acceptable salt thereof, optionally a corticosteroid, and optionally an anticholinergic ~~atropine-like~~ compound, in solution in a propellant system, said propellant system consisting of a liquefied HFA propellant, a co-solvent, a mineral acid and 0 to 5% w/w water,

wherein said cosolvent is present in an amount which is no more than 35% w/w based on the total weight of said formulation, and

wherein said formulation has a pH of 2.5 to 5.5, and

wherein said pH of said formulation has been adjusted by addition of said mineral acid.

Claim 2 (previously presented): A pharmaceutical formulation according to claim 1, which contains, as said cosolvent, at least one member selected from the group consisting of a lower alkyl (C1-C4) alcohol, a polyol, a polyalkylene glycol, a (poly)alkoxy alcohol, and mixtures thereof.

Claim 3 (previously presented): A pharmaceutical formulation according to claim 2, which contains ethanol.

Claim 4 (previously presented): A pharmaceutical formulation according to claim 3, wherein said water is present in an amount of 0.5% to 5% w/w and said ethanol is present in an amount of no more than 25% w/w.

Claim 5 (previously presented): A pharmaceutical formulation according to claim 1, wherein said water is present in an amount up to 3% w/w.

Claim 6 (previously presented): A pharmaceutical formulation according to claim 1, wherein a fraction of particles equal to or less than 1.1 μm delivered on actuation of an inhaler, which contains said formulation, is higher than or equal to 30% as defined by the content of the stages S6-AF of an Andersen Cascade Impactor, relative to the content of the stages S3-AF of an Andersen Cascade Impactor.

Claim 7 (previously presented): A pharmaceutical formulation according to claim 1, wherein said fraction of particles equal to or less than 1.1 μm delivered on actuation of said inhaler is higher than 40%.

Claim 8 (previously presented): A pharmaceutical formulation according to claim 1, wherein said physiologically acceptable salt of salmeterol is salmeterol xinafoate.

Claim 9 (previously presented): A pharmaceutical formulation according to claim 8, wherein salmeterol xinafoate is present in a concentration of 0.005 to 0.15% w/v.

Claims 10-11 (canceled).

Claim 12 (previously presented): A pharmaceutical formulation according to claim 1, which contains one or more hydrofluoroalkanes selected from the group consisting of HFA 134a, HFA 227, and mixtures thereof.

Claim 13 (previously presented): A pharmaceutical formulation according to claim 1, wherein the concentration of salmeterol is 0.04% w/v, the concentration of ethanol is 15% w/w, and the concentration of water is 2% w/w.

Claim 14 (previously presented): A pharmaceutical formulation according to claim 1, filled in a canister having part or all of its internal metallic surfaces made of standard aluminium, stainless steel, anodised aluminium or lined with an inert organic coating.

Claim 15 (canceled).

Claim 16 (Currently Amended): A method of preparing a pharmaceutical formulation according to claim 1, said method comprising:

- (a) preparing a solution of salmeterol, a stereoisomer thereof, or a physiologically acceptable salt thereof, optionally a corticosteroid, and optionally an anticholinergic ~~atropine-~~like derivative, in one or more co-solvents;
- (b) adjusting the pH of said formulation to 2.5 to 5.5 by addition of a mineral acid;
- (c) optionally adding 0 to 5% w/w of water;
- (d) filling a device with said solution;
- (e) crimping said device with a valve and gassing; and
- (f) adding a propellant containing a hydrofluoroalkane.

Claim 17 (previously presented): A method according to claim 16, wherein said device is provided with a valve actuator whose orifice diameter is 0.22 mm.

Claim 18 (withdrawn): A method for the treatment of a respiratory disease selected from the group consisting of chronic obstructive pulmonary disease, asthma, a disease due to obstruction of peripheral airways as a result of inflammation or mucus hypersecretion, pulmonary edema or a surfactant-deficiency related disorder, acute lung injury or acute respiratory distress syndrome, comprising administering an effective amount of a pharmaceutical formulation according to claim 1 to a subject in need thereof.

Claim 19 (withdrawn): A method according to claim 18, wherein said respiratory disease is asthma or chronic obstructive pulmonary disease.

Claim 20 (withdrawn): A method according to claim 19, wherein said respiratory disease is due to obstruction of peripheral airways as a result of inflammation or mucus hypersecretion.

Claim 21 (withdrawn): A method according to claim 18, wherein said respiratory disease is pulmonary edema or a surfactant-deficiency related disorder.

Claim 22 (withdrawn): A method according to claim 18, wherein said respiratory disease is acute lung injury or acute respiratory distress syndrome.

Claim 23 (currently amended): A pharmaceutical formulation according to claim 1, wherein said anticholinergic ~~atropine-like~~ compound is ipratropium bromide, oxitropium bromide or tiotropium bromide.

Claim 24 (currently amended): A pharmaceutical formulation according to claim 1, in which ~~contains~~ said corticosteroid is present.

Claim 25 (currently amended): A pharmaceutical formulation according to claim 1, in which ~~contains~~ said anticholinergic ~~atropine-like~~ compound is present.

Claim 26 (previously presented): A method for the treatment of a asthma, comprising administering an effective amount of a pharmaceutical formulation according to claim 24 to a subject in need thereof.

Claim 27 (previously presented) A method for the treatment of a chronic obstructive pulmonary disease, comprising administering an effective amount of a pharmaceutical formulation according to claim 25 to a subject in need thereof.